

Patent

IN THE CLAIMS

The listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Original) A method for identifying preferred control parameters for use in controlling an implantable cardiac stimulation device for implant within a patient, the method comprising the steps of:
 - controlling the implantable device to deliver therapy to the heart of the patient while switching among sets of control parameters during a series of consecutive evaluation periods that are substantially equal in duration to one another;
 - detecting values representative of transient cardiac performance corresponding to the different sets of control parameters; and
 - estimating optimal control parameters for maximizing cardiac performance based on the values representative of transient cardiac performance.
2. (Currently Amended) The method of claim 1 wherein the evaluation periods are sufficiently short so that [[so that]] hemodynamic feedback systems of the patient do not have time to readjust the cardiovascular system of the patient to a substantially equilibrium state before the control parameters are switched again.
3. (Original) The method of claim 1 wherein the evaluation periods are no longer than 12 seconds each.
4. (Currently Amended) The method of claim 1 wherein the evaluation periods are no longer than two respiratory cycles each, wherein a respiratory cycle comprises one inspiration and one expiration.

Patent

5. (Original) The method of claim 2 wherein the step of detecting values representative of transient cardiac performance is performed to detect changes in transient cardiac performance from one consecutive evaluation period to another; and wherein the step of estimating the optimal set of control parameters is performed based on the changes in transient cardiac performance.
6. (Original) The method of claim 5 wherein the step of detecting changes in transient cardiac performance comprises the steps of:
measuring values representative of transient cardiac performance of the heart of the patient during each evaluation period; and
determining the difference in transient cardiac performance based on a comparison of the measured values.
7. (Currently Amended) The method of claim 6 wherein the periods of time over which the values representative of transient cardiac performance are measured are each set equal to substantially identical portions of a respiratory cycle, wherein a respiratory cycle comprises one inspiration and one expiration.
8. (Currently Amended) The method of claim 6 wherein the periods of time over which the values representative of transient cardiac performance are measured are each set equal to about four seconds.
9. (Currently Amended) The method of claim 6 wherein the step of controlling the implantable device to deliver therapy to the heart of the patient while switching among sets of control parameters using different sets of control parameters is performed comprises controlling the implantable device to deliver therapy to the heart of the patient by alternating, from one evaluation period to another, between different sets of selected test control parameters and a set of reference control parameters.
10. (Original) The method of claim 9 wherein the step of determining the difference in transient cardiac performance based on a comparison of the measured

Patent

values includes the steps performed, for each evaluation period employing test control parameters, of:

- generating a first difference value representative of a change in average transient cardiac performance between the prior reference evaluation period and the given evaluation period;
- generating a second difference value representative of a change in average transient cardiac performance between the given evaluation period and the subsequent reference evaluation period and reversing the sign of the second difference value such that a pair of first and second difference values are generated for each evaluation period.

11. (Original) The method of claim 10 wherein the step of estimating the optimal set of control parameters includes the steps of:

- associating each pair of first and second difference values with the set of control parameters employed during the corresponding evaluation period;
- fitting a curve to the difference values versus associated test parameter values; and
- identifying the set of control parameters providing a maximal difference value as indicated by the curve.

12. (Original) The method of claim 6 wherein the step of controlling the implantable device to deliver therapy using different sets of control parameters is performed by cycling through different sets of selected test control parameters to provide for all possible changes between sets of control parameters.

13. (Original) The method of claim 6 wherein the step of controlling the implantable device to deliver therapy using different sets of control parameters is performed by cycling through different sets of selected test control parameters to provide for only a sub-set of all possible changes between sets of control parameters.

Patent

14. (Original) The method of claim 6 wherein the step of determining the difference in transient cardiac performance based on a comparison of the measured values includes the steps of:

- detecting a value representative of transient cardiac performance during an immediately preceding evaluation period;
- detecting a value representative of transient cardiac performance during the given evaluation period; and
- generating a difference value representative of a change in transient cardiac performance between the prior evaluation period and the given evaluation period such that a single difference value is generated for each evaluation period.

15. (Original) The method of claim 14 wherein the step of estimating the optimal set of control parameters includes the steps of:

- associating each difference value with the set of control parameters employed during the corresponding evaluation period;
- fitting a single curve to the difference values versus associated test parameter values; and
- identifying a set of preferred control parameters providing maximal difference values as indicated by the single curve.

16. (Original) The method of claim 14 wherein the step of estimating the optimal set of control parameters includes the steps of:

- associating each difference value with the set of control parameters employed during the corresponding evaluation period;
- for each set of control parameters, fitting a separate curve to the difference values versus the set of parameter values; and
- for each set of control parameters, identifying a separate set of preferred control parameters providing maximal difference values as indicated by the separate curve; and
- averaging the separate sets of preferred control parameters together to yield a single set of control parameters.

Patent

17. (Original) The method of claim 1 wherein the step of controlling the implantable device to deliver therapy while ~~[[changing]]~~ switching control parameters is performed to adaptively adjust the control parameters based on resulting changes in cardiac performance; and wherein the step of estimating optimal control parameters for maximizing cardiac performance ~~for use in delivering further therapy is performed to identify~~ comprises identifying control parameters that result in the most positive difference in cardiac performance as compared to all other control parameter values.
18. (Original) The method of claim 1 wherein the control parameters include one or more of: pacing base rate; maximum tracking rate; minimum tracking rate; atrioventricular (AV) delay and interventricular delay.
19. (Currently Amended) The method of claim 1 wherein the step of detecting values representative of transient cardiac performance is performed to detect values representative of one or more of stroke volume, cardiac output, end-diastolic volume, end-systolic volume, ejection fraction, cardiac output index, flow through the mitral valve, maximum rate of change of left ventricular pressure with time, maximum rate of change of aortic pressure with time, mean arterial pressure, arterial pulse pressure, vascular volume, and vascular photoplethysmography.
20. (Original) The method of claim 1 further including the initial step of determining whether to initiate an optimization procedure based on a change in one or more of patient posture, heart rate, activity levels, autonomic tone, and fluid status.
21. (Original) The method of claim 1 wherein the steps of the method are performed periodically.

Patent

22. (Original) The method of claim 1 wherein the step of controlling the implantable device to deliver therapy to the heart of the patient while changing control parameters is performed by an external programmer device.

23. (Original) The method of claim 1 wherein all steps of the method are performed by the implantable device.

24. (Withdrawn) An implantable system for identifying preferred control parameters for use in controlling delivery of cardiac stimulation therapy to a patient, the system comprising:

- an on-board control parameter optimizer operative to control the implantable device to deliver therapy to the heart of the patient while switching among sets of control parameters during a series of consecutive evaluation periods that are substantially equal in duration to one another; and

- a sensor data input unit operative to input signals representative of transient cardiac performance of the heart of the patient from a sensor; and wherein the

- on-board control parameter optimizer is further operative to estimate an optimal set of control parameters based on the values representative of transient cardiac performance.

25. (Withdrawn) An external system for identifying preferred control parameters for use in controlling an implantable cardiac stimulation device for implant within a patient, the system comprising:

- a parameter optimizer controller implemented within an external programmer device and operative to control the implantable device to deliver therapy to the heart of the patient while switching among sets of control parameters during a series of consecutive evaluation periods that are substantially equal in duration to one another; and

Patent

an external hemodynamic sensing system operative to detect values representative of transient cardiac performance of the heart of the patient; and wherein the parameter optimizer controller is further operative to estimate an optimal set of control parameters based on the values representative of transient cardiac performance.

26. (Withdrawn) A system for identifying preferred control parameters for use in controlling an implantable cardiac stimulation device for implant within a patient, the system comprising:

means for controlling the implantable device to deliver therapy to the heart of the patient using different sets of control parameters, with parameters changed sufficiently quickly so that hemodynamic feedback systems of the patient do not have time to significantly affect transient cardiac performance achieved at each set of control parameters before the parameters are switched again;

means for detecting values representative of transient cardiac performance of the heart of the patient corresponding to the different sets of control parameters; and

means for controller is also operative to estimate an optimal set of control parameters for use in delivering further therapy based on the values representative of transient cardiac performance.

27. (Withdrawn) A method for updating preferred control parameters for use in controlling an implantable cardiac stimulation device for implant within a patient, the method comprising the steps of:

detecting a change in patient status; and

responsive to the detection of the change in patient status, performing a control parameter optimization procedure wherein optimal control parameters are identified based on transient cardiac performance detected while switching among sets of control parameters during a

Patent

series of consecutive evaluation periods that are substantially equal in duration to one another.

28. (Withdrawn) The method of claim 27 wherein the step of detecting a change in patient status is performed to detect a change in one or more of: patient posture; heart rate and activity level.

29. (Withdrawn) The method of claim 27 wherein the step of the performing the control parameter optimization procedure is also triggered periodically if no change in patient status is otherwise detected within a predetermined period of time.

30. (Withdrawn) A method for identifying preferred control parameters for use in controlling an implantable cardiac stimulation device for implant within a patient, the method comprising the steps of:

controlling the implantable device to deliver therapy to the heart of the patient while switching among sets of control parameters sufficiently quickly so that hemodynamic feedback systems of the patient do not have time to return the hemodynamic system of the patient to a substantially equilibrium state before the control parameters are switched again; detecting values representative of transient cardiac performance corresponding to each switch in control parameters; and estimating optimal control parameters for maximizing cardiac performance based on the values representative of transient cardiac performance.